## REMARKS

### I. Support for the Amendments

Claims 1, 5-8, 11, and 17 are presently in the application. Claims 1, 6, 8, and 11 have been amended. Claims 2-4 have been canceled without prejudice to their pursuit in an appropriate continuation or divisional application.

Support for amended claims 1, 6, 8, and 11 can be found in the original specification and claims. Additional support for amended claims 1, 6, 8, and 11 can be found, e.g., from page 14, line 19, to page 15, line 2; and in the Examples.

### II. Status of the Claims

Claims 1-14 were originally in the application, with claim 1 being the independent claim. Claims 1-14 were subject to an Election/Restriction Requirement, and claims 1-8 and 11 (Group I) were elected with traverse.

Previously, claims 1-8, 11, and 17 were in the application. Claims 1 and 11 were the independent claims. Claims 9-10 and non-elected claims 12-14 were canceled without prejudice to their pursuit in an appropriate continuation or divisional application.

Claims 1, 5-8, 11, and 17 are currently in the application. Claims 1, 6, 8, and 11 have been amended. Claims 5-7 are dependent on claim 1, and claim 17 is dependent on claim 11. Claims 2-4 have been canceled without prejudice to their pursuit in an appropriate continuation or divisional application.

## III. Receipt of the Priority Documents

Applicants thank the Examiner for acknowledging receipt of the priority documents.

## IV. The Information Disclosure Statements are Acknowledged

Applicants thank the Examiner for acknowledging the Information Disclosure Statements.

## V. The Objection to the Specification is Withdrawn

Applicants thank the Examiner for withdrawing the objection to the specification.

## VI. The Objections to Claims 2-4 and 8 are Accommodated in Part and Rendered Moot in Part

The Examiner has objected to claims 2-4 as outlined in the Office Action. Applicants have canceled claims 2-4 without prejudice to their pursuit at a later time, thereby rendering the objection to these claims moot. Applicants reserve the right to pursue these claims in the future.

The Examiner has objected to claim 8 for the typographical error ("UDP-2"). Accordingly, Applicants have corrected this informality to read "UCP-2."

## VII. The Rejection of Claims 1-8, 11, and 17 under 35 U.S.C. §112, Second Paragraph is Accommodated in Part and Rendered Moot in Part

The Examiner has rejected claims 1-4 and 11 under 35 U.S.C. §112, second paragraph (pp. 4-7). The Examiner has rejected claims 5-8 and 17 as dependent on claims 1-4 and 11. These are new rejections.

The Patent Office has the following new rejection of claim 1:

> Claim 1 is vague and indefinite in that the metes and bounds of "or part" are unclear: does Applicant intend for the UCP-2 promoter region to encompass a single part of the base sequence consisting of nucleotides 1 to 2270 of SEQ ID NO: 1, wherein the part of the base sequence comprises a regulator sequence selected from a-d; or does the claim encompass discontiguous parts as long as one part meets the rest of the claim limitations? The indefinite nature of the first reference to "part" in claim one makes the antecedent basis of "the part" recited in line 4 improper. [P. 5.]

Applicants respectfully submit that the present claim 1 addresses all of the Examiner's remarks. Claims 5-8 are dependent on claim 1, and the amended language of claim 1 also applies to these claims.

Claims 2-4 have been canceled without prejudice, and Applicants respectfully submit that the rejection is rendered moot with respect to these claims.

The Patent Office has the following new rejection of claim 11:

> Claim 11 is vague and indefinite in that the metes and bounds of "or part" are unclear as described above for claim 1. Also, as recited above, the indefinite nature of the first reference to "part" in claim 11 makes the antecedent basis of "the part" recited in line 11 improper. [P. 7.]

Applicants respectfully submit that the present claim 11 addresses all of the Examiner's remarks and clearly delineate the metes and bounds of claimed invention with respect to the UCP-2 promoter sequence. Claim 17 is dependent on claim 11, and the amended language of claim 11 also applies to this claim.

Furthermore, Applicants respectfully submit that, in amended claims 1 and 11, the "part of the base sequence" is limited to a (contiguous) sequence consisting of the sequence described from page 14, line 19, through page 15, line 2, of the specification. Thus, Applicants submit that the metes and bounds of the "part of the base sequence" are clear.

Applicants respectfully submit that claims 1, 5-8, 11, and 17 fulfill the requirements of 35 U.S.C. §112, second paragraph, thereby placing these claims in condition for allowance.

**VIII. The Rejection of Claims 8, 11, and 17 Under 35 U.S.C. §112, First Paragraph, is Traversed, but Accommodated in Part**

The Examiner has rejected claims 8 and 11 under 35 U.S.C. §112, first paragraph, with respect to the written description requirement (pp. 7-13) and claim 17 as dependent on claim 11. These are new rejections. Applicants respectfully disagree.

The Patent Office alleges:

> **[T]here is insufficient description of the broad genus of nucleic acids encompassed by the term "UCP-2 promoter" and the corresponding "UCP-2 promoter activity" to reasonably convey to the skilled artisan that Applicant had possession of the broadly claimed invention at the time of filing.** [P. 8; emphasis in original.]

The Patent Office also alleges:

> Other than to say that the "UCP-2 promoter was found in the 3.3 kb DNA of the upstream region of the human UCP-2 structural gene," no information is provided in the specification regarding the boundaries for what is considered a UCP-2 promoter. Moreover, there is no limitation in the rejected claim that the cited terms are limited to the human UCP-2 promoter, even if such boundaries were clearly defined in the instant specification for the human promoter region. While claim 1 recites that the promoter region comprises nucleotides 1-2270 of SEQ ID NO: 1, it also encompasses embodiments that are just part of SEQ ID NO: 1 as long as the part includes a regulator sequence selected from the recited PPRE, C/EPB, GRE and Myo-D binding sequences. Thus, the rejected claims read on an extremely large number of different nucleic acid sequences. [Pp. 9-10.]

Applicants respectfully disagree for reasons already on record with respect to a similar rejection in the previous Office Action, but have amended claims 8 and 11. The language of claims 8 and 11 is as follows:

> 8 (currently amended). A method for screening for a compound or its salt that promotes or inhibits a human UCP-2 promoter activity, which comprises:
>
> a. measuring the expression level of structural gene in a transformant, with a human UCP-2 promoter sequence, contacted to a first sample of the compound or its salt and that in a control transformant, with no human UCP-2 promoter, contacted to a second sample of the compound or its salt, wherein the human UCP-2 promoter sequence consists of all or a part of a base sequence consisting of nucleotides 1 to 2270 of SEQ ID NO: 1, wherein the part of the base sequence consists of nucleotides 255 to 430 of SEQ ID NO: 1, nucleotides 255 to 717 of SEQ ID NO: 1, nucleotides 717 to 1133 of SEQ ID NO: 1, nucleotides 1133 to 1389 of SEQ ID NO: 1, nucleotides 255 to 1857 of SEQ ID NO: 1, nucleotides 571 to 2270 of SEQ ID NO: 1, nucleotides 717 to 2270 of SEQ ID NO: 1, nucleotides 1133 to 2270 of SEQ ID NO: 1, nucleotides 1389 to 2270 of SEQ ID NO: 1, or nucleotides 1634 to 2270 of SEQ ID NO: 1; and

b. comparing the expression levels thereof.

11 (currently amended). A kit for screening for a compound or its salt that promotes or inhibits a human UCP-2 promoter activity, which comprises:

a. a medium for culturing a host animal cell line;

b. a plasmid for measurement of the human UCP-2 promoter activity, which comprises:

i. plasmid DNA carrying a human UCP-2 promoter sequence wherein the human UCP-2 promoter sequence consists of all or a part of the base sequence consisting of nucleotides 1 to 2270 of SEQ ID NO: 1, wherein the part of the base sequence consists of nucleotides 255 to 430 of EQ ID NO: 1, nucleotides 255 to 717 of SEQ ID NO: 1, nucleotides 717 to 1133 of SEQ ID NO: 1, nucleotides 1133 to 1389 of SEQ ID NO: 1, nucleotides 255 to 1857 of SEQ ID NO: 1, nucleotides 571 to 2270 of SEQ ID NO: 1, nucleotides 717 to 2270 of SEQ ID NO: 1, nucleotides 1133 to 2270 of SEQ ID NO: 1, nucleotides 1389 to 2270 of SEQ ID NO: 1, or nucleotides 1634 to 2270 of SEQ ID NO: 1; and

ii. a structural gene inserted downstream of the human UCP-2 promoter; and

c. a host animal cell line.

In amended claims 8 and 11, "UCP-2 promoter" has been limited to that derived from humans. A "human UCP-2 promoter sequence" has also been specified to a sequence consisting of nucleotides 1 to 2270 of SEQ ID NO: 1 or a sequence consisting of a sequence specifically described on page 14, line 19, through page 15, line 2, of the specification. These "human UCP-2 promoter sequences" include one or more specific regulator sequences described on page 14, lines 1-14, of the specification.

In the EXAMPLES of the present application, there are descriptions about (i) preparation of seven kinds of deletion mutants, wherein one or more specific regulator sequences are deleted; (ii) verification of these promoter activities; and (iii) the fact that the promoter activities are maintained other than that of mutant wherein upstream sequence from initiation site of transcription are completely deleted.

Thus, Applicants respectfully submit that the person skilled in the art would understand that (a) the "UCP-2 promoter sequence" described in amended claims 8 and 11 possess a promoter activity caused by one or more regulator sequence in the sequence; and (b) by using these sequences, a compound that acts on any regulator sequence in the sequence to regulate UCP-2 expression can be screened.

Claim 17 is dependent on claim 11, and the amended language of claim 11 also applies to this claim.

Applicants respectfully submit that claims 8, 11, and 17 fulfill the requirements of 35 U.S.C. §112, first paragraph, thereby placing these claims in condition for allowance.

## IX. The Rejection of Claims 1-8 Under 35 U.S.C. §102(b) Is Traversed

The Examiner has maintained the rejection of claims 1-8 under 35 U.S.C. §102(b) alleging anticipation by Surwit et al. (WO 98/31396; see the entire PCT application). Applicants respectfully disagree.

The Patent Office reiterates the previous rejection and further alleges:

> The teachings of Surwit et al are also disclosed in U.S. 2003/0119775 Al. The US application does not appear to comprise a sequence listing that discloses the relevant sequences so that the Examiner could do the comparison for Applicant. However, arguments directed to an undue burden placed upon Applicant in this regard are irrelevant. Applicant's response has not effectively rebutted Examiner's argument that one would necessarily expect the clones disclosed by Surwit et al to possess the recited structural and functional characteristics. As indicated in the record, the Office does not have the facilities for examining and comparing an applicant's claimed product with the products of the prior art, and the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art. See In *re Best,* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Applicants respectfully disagree with these comments, in addition to those from the previous Office Action, and traverse the anticipation rejection, in part for reasons already on record.

Furthermore, Applicants respectfully submit that the Patent Office has not met the burden of proof for making a prima facie showing that the sequences recited in claim 1 are expressly disclosed in Surwit. Applicants have already provided rebuttal evidence in previously submitted Exhibit A. With respect to the argument by the Patent Office that the U.S. application of Surwit does not include a sequence listing, Applicants respectfully submit that the Patent Office is in a position to require submission of a sequence listing for the sake of comparison and that the request for a sequence listing would be much less burdensome to the Patent Office than the unduly burdensome requirement to obtain a cell line, isolate the nucleic acid in question, and sequence it would be for the Applicants.

The present language of claims 1 and 8 reads as follows:

1 (currently amended). An isolated DNA comprising a human uncoupling protein-2 (UCP-2) promoter region, which consists of all or a part of a base sequence consisting of nucleotides 1 to 2270 of SEQ ID NO: 1, wherein the part of the base sequence consists of nucleotides 255 to 430 of SEQ ID NO: 1, nucleotides 255 to 717 of SEQ ID NO: 1, nucleotides 717 to 1133 of SEQ ID NO: 1, nucleotides 1133 to 1389 of SEQ ID NO: 1, nucleotides 255 to 1857 of SEQ ID NO: 1, nucleotides 571 to 2270 of SEQ ID NO: 1, nucleotides 717 to 2270 of SEQ ID NO: 1, nucleotides 1133 to 2270 of SEQ ID NO: 1, nucleotides 1389 to 2270 of SEQ ID NO: 1, or nucleotides 1634 to 2270 of SEQ ID NO: 1.

8 (currently amended). A method for screening for a compound or its salt that promotes or inhibits a human UCP-2 promoter activity, which comprises:

a. measuring the expression level of structural gene in a transformant, with a human UCP-2 promoter sequence, contacted to a first sample of the compound or its salt and that in a control transformant, with no human UCP-2 promoter, contacted to a second sample of the compound or its salt, wherein the human UCP-2 promoter sequence consists of all or a part of a base sequence consisting of

nucleotides 1 to 2270 of SEQ ID NO: 1, wherein the part of the base sequence consists of nucleotides 255 to 430 of SEQ ID NO: 1, nucleotides 255 to 717 of SEQ ID NO: 1, nucleotides 717 to 1133 of SEQ ID NO: 1, nucleotides 1133 to 1389 of SEQ ID NO: 1, nucleotides 255 to 1857 of SEQ ID NO: 1, nucleotides 571 to 2270 of SEQ ID NO: 1, nucleotides 717 to 2270 of SEQ ID NO: 1, nucleotides 1133 to 2270 of SEQ ID NO: 1, nucleotides 1389 to 2270 of SEQ ID NO: 1, or nucleotides 1634 to 2270 of SEQ ID NO: 1; and

b. comparing the expression levels thereof.

Applicants respectfully submit that claims 1 and 8 in their present form are not anticipated by Surwit (WO 98/31396). The present application discloses promoter activity for the human UCP-2 gene and provides specific regulator sequences and experimental data regarding the same, including deletion mutants (see, e.g., p. 14, line 1, to p. 15, line 2, and the Examples).

"An isolated DNA comprising a human uncoupling protein-2 (UCP-2) promoter region" in amended claim 1, and "a human UCP-2 promoter sequence" in amended claim 8 have been specified to a sequence consisting of nucleotides 1 to 2270 of SEQ ID NO: 1 or a sequence consisting of a sequence specifically described on page 14, line 19 through page 15, line 2 of the specification as described above. The sequence described in amended claim 1 is a contiguous and specific sequence having 175 to 2270 nucleotides. Applicants submit that Surwit's clones do not inherently possess the aforementioned sequence.

Applicants respectfully submit that the present claim 1 addresses all of the Examiner's remarks. Claims 5-8 are dependent on claim 1, and the amended language of claim 1 also applies to these claims. Claim 8 has also been amended.

Claims 2-4 have been canceled without prejudice, and Applicants respectfully submit that the rejection is rendered moot with respect to these claims.

Applicants respectfully submit that the present claims 1 and 5-8 fulfill the requirements of 35 U.S.C. §102(b) and request the Examiner's reconsideration of these claims accordingly.

## X. Conclusion

It is believed that all outstanding rejections have been addressed by this submission and that all the claims are in condition for allowance. If discussion of any amendment or remark made herein would advance this important case to allowance, the Examiner is invited to call the undersigned as soon as convenient.

In view of the foregoing amendments and remarks, the present application is respectfully considered in condition for allowance. An early reconsideration and notice of allowance are earnestly solicited.

It is believed that no extension of time is required for the filing of the Amendment. If an extension of time is required, Applicants hereby request the Examiner to consider this a conditional petition for an extension of time. Although it is not believed that any additional fee (in addition to the fee concurrently submitted) is required to consider this submission, the Commissioner is hereby authorized to charge our deposit account no. 04-1105 should any fee be deemed necessary.

Respectfully submitted,

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